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APPLICATION FOR LETTERS PATENT

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| INVENTION | : | PROSTHESIS FOR INTERNAL PERITONEAL DIALYSIS AND METHOD OF PROVIDING PERITONEAL DIALYSIS |
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TO ALL WHOM IT MAY CONCERN:

Be it known that I, John M. Levin, a citizen of the United States of America, residing in the town of Narberth, County of Montgomery, Commonwealth of Pennsylvania, have made a certain new and useful invention in a Prosthesis for Internal Peritoneal Dialysis and Method of Providing Peritoneal Dialysis as set forth above of which the following is a specification.

## SPECIFICATION

This application is a Continuation-In-Part of United States Patent Application No. 09/833,286, filed April 12, 2001, and entitled "Prosthesis for Internal Peritoneal Dialysis and Method of Providing Peritoneal Dialysis"; which is a Continuation-In-Part of United States Patent Application No. 09/693,591, filed October 20, 2000, and entitled "Prosthesis for Continuous Internal Peritoneal Dialysis and Continuous Method of Providing Peritoneal Dialysis."

## FIELD OF THE INVENTION

This invention relates to generally to prosthesis for continuous internal peritoneal dialysis and a continuous method of carrying out peritoneal dialysis. More specifically, this invention relates to artificial kidneys, and more specifically to artificial kidneys implantable within a person's body with the intent that the patient be free from dialysis and transplantation. The artificial kidneys of this invention employ the normal operation of the person's body (*i.e.*, breathing cycle of the person) to cause the flow of fluid within the prosthesis for the removal of toxic substances or other fluids from the person's body. For the treatment of edema states that are refractory to treatment with diuretics the dialysate can be a selected hypertonic solution for removing excess fluids; principally water.

## BACKGROUND OF THE INVENTION

The dialysis art is a highly developed one; providing a variety of teachings for dialyzing a patient.

In accordance with a related dialysis procedure (*e.g.*, hemodialysis) for purifying blood in a patient experiencing kidney failure, the contaminated blood is directed from a blood vessel of the patient's arm through a dialyzing membrane located extracorporeally of the body, in which the blood gives up its impurities to the dialyzing fluid. The purified blood is then directed back into the patient's body through another blood vessel. A representative disclosure of a system for use in purifying arterial blood and providing a venous return is disclosed in U.S. Patent No. 3,579,441, issued to Brown.

The dialysis art also suggests the use of related peritoneal dialysis systems, wherein a dialysate is introduced directly into the abdomen of the patient and functions to receive impurities from the blood at the abdominal capillaries, and then is mechanically removed from the body. Representative peritoneal dialysis systems of this type are disclosed in U.S. Patent Numbers: 4,681,564 (Landreneau); 4,655,762 (Rogers); 4,586,920 (Peabody) and 4,437,856 (Valli).

All of the related art systems known to applicants suffer from one or more disadvantages. For example, a number of prior art systems require that the patient be connected, *e.g.*, "hooked-up", to a dialysis machine. This renders the patient immobile during treatment, is expensive to administer, and subjects the patient to a high risk of infection, and even death. Patients are protein restricted, because protein yields toxic degradation products (*e.g.*, nitrogenous wastes) largely responsible for uremia, the state of being in kidney failure. Toxic levels of potassium may also result from the treatment. Moreover, chronic contact of the peritoneum with hypertonic dialysate solutions often

creates chronic peritonitis, which is a painful, dangerous condition that interferes with the peritoneal dialysis process.

The absorption of dialysate into the bloodstream interferes with the peritoneum dialysate's ability to do its job of pulling in fluids. Therefore, peritoneal dialysis relies physiologically on the fact that the dialysis fluid in the abdominal cavity is more viscous or thicker than blood. In other words, the dialysis fluid has a higher osmolality or chemical potential than the bloodstream. This difference in potential causes water and other molecules known to those skilled in the art to diffuse into the abdomen via the semi-permeable membranes of the peritoneum and mesenteric parietes which line the abdominal cavity.

Additionally, all previous modes of dialysis have been essentially intermittent, rather than continuous; resulting in a variety of disturbances to the body's equilibrium. Patients become either over-hydrated or under-hydrated due to the intermittent process of adding and removing fluids. The systems can not maintain proper blood volume and chemical balance beyond the few hours following the treatment. The treatments sap the patient's energy and sense of well-being, making the patient look and feel chronically ill, and critically affecting the patient's lifestyle, happiness and longevity.

With respect to transplantation, the high cost and risks are well known. A match for the patient must be found, which may take years. If a kidney is found, and the patient is still strong enough to receive it, then there is no guarantee that the kidney will be accepted. The patient's immune system may recognize a kidney transplanted from

another as foreign matter and act to combat and reject this perceived invasion. Anti-rejection medication, such as azathioprine, cyclosporine and steroids help to prevent rejection. However, anti-rejection medicines have a large number of side effects. If rejection occurs, treatment is available to possibly reverse the episode, but at the cost of more medication and side effects. With kidney transplantation, about one third of the patients do very well, about one third remain chronically ill, and about one third of the patients die within five years.

A need clearly exists for an artificial kidney, or prosthesis, that is lower in cost than existing systems, that can be utilized with a minimum of risk to the patient, that provides greater freedom of movement for the patient and that allows for the continuous formation of urine as in a normal functioning kidney. Therefore, it would be beneficial to provide a continuous internal peritoneal dialysis prosthesis and method. It would also be beneficial to provide a continuous internal peritoneal dialysis prosthesis and method which employs the normal breathing pattern of the patient to affect the dialysis operation, which is simple in operation and requires relatively few moving parts.

To applicant's knowledge, prior to this invention, there has been no artificial kidney that is implantable in the body to provide any of the functions normally provided by a healthy kidney. It is to such artificial kidneys that the present invention is directed.

## SUMMARY OF THE INVENTION

This invention includes a continuous internal peritoneal dialysis prosthesis and method employing an abdominal sac including a dialysate therein, the abdominal sac being adapted to be retained in the abdominal region of a person's body for receiving unconcentrated urine through the walls of the sac without permitting dialysate to exit from the sac through the walls. The abdominal sac communicates the unconcentrated urine through a section of the patient's bowel via at least one conduit that extends through the section of bowel. A region of the conduit within the section of the patient's bowel includes apertures therein for communicating the unconcentrated urine in the conduit with walls of the section of bowel; thereby employing the natural function of the bowel to concentrate the urine.

In another preferred embodiment, this invention includes a continuous internal peritoneal dialysis prosthesis and method employing an abdominal sac, a fluid guide conduit and a conduit extension. The abdominal sac is adapted to include a dialysate therein. The abdominal sac includes a semi-permeable membrane outer wall, and is adapted to be retained in the abdominal region of a patient's body with the semi-permeable membrane outer wall being in communication with unconcentrated urine in the abdominal region for receiving unconcentrated urine through the semi-permeable membrane outer wall without permitting dialysate to exit through the outer wall. The fluid guide conduit is adapted to receive the unconcentrated urine and dialysate from the abdominal sac and to communicate the dialysate back into the abdominal sac for

recirculation. The conduit extension extends from the fluid guide conduit and is adapted to receive the unconcentrated urine from the fluid guide conduit. The conduit extension is also adapted to extend into and terminate in a section of the patient's bowel separated from the patient's GI tract to communicate the unconcentrated urine in the conduit extension with the section of bowel for concentrating the urine within the section of bowel.

A continuous internal peritoneal dialysis method of this invention includes containing unconcentrated urine in the abdominal region of a patient, and directing the contained unconcentrated urine into a section of bowel in which the urine is concentrated for removal from the patient.

Further scope of applicability of the present invention will become apparent from the description given hereinafter. However, it should be understood that the detailed description and specific examples, while indicating preferred embodiments of the invention, are given by way of illustration only, since the invention will become apparent to those skilled in the art from this detailed description.

## BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described in conjunction with the following drawings in which like reference numbers designate like elements, and wherein:

Fig. 1 is a front view of a continuous internal peritoneal dialysis prosthesis of a preferred embodiment of the present invention showing parts thereof in section and being located in a person's body;

Fig. 2 is a front view of a continuous internal peritoneal dialysis prosthesis of another preferred embodiment of the present invention showing parts thereof in section and being located in a person's body;

Fig. 3 is a front view of a continuous internal peritoneal dialysis prosthesis of a third embodiment of the present invention showing parts thereof in section and being located in a person's body;

Fig. 4 is a front view of a continuous internal peritoneal dialysis prosthesis of a fourth embodiment of the present invention showing parts thereof in section and being located in a person's body;

Fig. 5 is a front view of a continuous internal peritoneal dialysis prosthesis of a fifth embodiment of the present invention showing parts thereof in section and being located in a person's body;

Fig. 6 is a front view of an internal peritoneal dialysis prosthesis of a sixth embodiment of the present invention showing parts thereof in section and being located in a person's body;

Fig. 7 is a front view of a continuous internal peritoneal dialysis prosthesis of a seventh embodiment of the present invention showing parts thereof in section and being located in a person's body;

Fig. 8 is a front view of a continuous internal peritoneal dialysis prosthesis of an eighth embodiment of the present invention showing parts thereof in section and being located in a person's body;

Fig. 9 is a front partial view of an internal peritoneal dialysis prosthesis of a ninth preferred embodiment of the present invention showing parts thereof in section; and

Fig. 10 is a front view of a continuous internal peritoneal dialysis prosthesis of a tenth embodiment of the present invention showing parts thereof in section and being located in a person's body.

## DETAILED DESCRIPTION OF THE INVENTION

Referring to Fig. 1, an exemplary continuous internal peritoneal dialysis prosthesis inserted within a patient's body is schematically illustrated at 10. The prosthesis 10 includes an abdominal sac 12 in the abdominal region of the patient below diaphragm 14, a thoracic pouch 16 in the thoracic region of a patient's body above the diaphragm 14 , a section of a patient's bowel 18 located within the abdominal section of the patient, and the patient's urinary bladder 20 connected to a downstream end of the bowel 18 through the patient's cecum or appendix 22 and distal right ureter 24.

Still referring to Fig. 1, the abdominal sac 12 is connected to the thoracic pouch 16 through a conduit 26 including a one-way valve 28 therein. The one-way valve 28 permits fluid (*e.g.*, unconcentrated urine) to flow only in the direction of arrow 30 from the abdominal sac 12 into the thoracic pouch 16.

The abdominal sac 12 includes a semi-permeable outer wall 56 and an impermeable outer wall 58 separated by a semi-permeable window 34. The region of the abdominal sac 12 defined by the semi-permeable outer wall 56 and the semi-permeable window 34 is a dialysis sac 32. The impermeable outer wall 58 includes a first port 60 for receiving a proximal end of the conduit 26. After the conduit 26 is in communication with the port 60, the wall of the abdominal sac 12 is stitched about the conduit 26 to retain the conduit within the port 60.

Still referring to Fig. 1, the prosthesis 10 includes a second conduit 36 that is connected to the thoracic pouch 16 and passes through the diaphragm 14 into and through

a section of the patient's bowel 18. The second conduit 36 also includes a one-way valve 38 to permit the unconcentrated urine to flow from the thoracic pouch 16 through the section of the patient's bowel 18 only in the direction of the arrow 40.

As can be seen in Fig. 1, the patient's bowel 18 includes end sections sutured to the conduit 36 at both the entrance 42 to the bowel 18 and the exit 44 from the bowel 18. The distal end 46 of the second conduit 36 extends through a lower end of the bowel 18 and is connected to the abdominal sac 12 to recycle the flow of unconcentrated (or partially concentrated) urine back into the abdominal sac 12, as will be described in greater detail below. The distal end 46 is provided with a one-way valve 48 to permit the urine to flow only in the direction of arrow 49 from the patient's bowel 18 to the abdominal sac 12.

As noted earlier, the abdominal sac 12 is formed of an impermeable membrane at outer wall 58, and a semi-permeable membrane at outer wall 56 and window 34. The semi-permeable outer wall 56 and window 34 define the dialysis sac 32 of the abdominal sac 12. The semi-permeable membrane has pores or apertures (holes) that provide the membrane with a porosity which precludes dialysate within the dialysis sac 32 from escaping into the peritoneal region, but still permits unconcentrated urine within the peritoneal region to enter the dialysis sac 32 through osmotic pressure. The porosity of the semi-permeable window 34 also precludes dialysate within the dialysis sac 32 from filtering through the semi-permeable window 34 into the region of the abdominal sac 12 in communication with the conduits 26 and 36. Therefore, in this example of the

preferred embodiment, the dialysate is contained within the dialysis sac 32. Because the abdominal sac 12 is required to function in an aqueous environment, it preferably is formed of a synthetic plastic material with some elastic qualities. However, the dialysis sac 32 should not be so elastic as to expand to an extent that permits the dialysate molecules or microstructures to exit from expanded pores of its walls.

In order to prevent the dialysis sac 32 from expanding to an extent that permits the dialysate to exit its walls, portions of the semi-permeable outer wall 56 and window 34 may alternatively be formed of an impermeable or substantially impermeable membrane that is more elastic than the semi-permeable membrane and does not permit the dialysate to exit, even when the impermeable or substantially impermeable membrane is expanded beyond its elastic limit. Therefore, before the semi-permeable membrane expands under pressure to an extent that could permit dialysate to exit, the impermeable or substantially impermeable membrane stretches to contain the dialysate while inhibiting the dialysate from exiting therefrom. Also, impermeable wall 58 could be made elastic and semi-permeable walls 56 and 34 inelastic.

In an exemplary environment of this invention, the dialysate exerts chemical potential to draw in unconcentrated urine (*e.g.*, fluid wastes, electrolytes, etc.) via the adjacent peritoneum and mesenteric parieties. The dialysate can be a large inert molecule or microstructure, *e.g.*, microspheres, such as a 50 micron polyelectrolyte or L-racemate of any giant inert molecule which cannot exit the sac. It should be understood that, in accordance with the broadest aspects of this invention, the specific dialysate employed

does not constitute a limitation on the present invention. However, the particle size of the dialysate must be such that the dialysate does not escape through the semi-permeable membrane walls of the dialysis sac 32 during operation of the prosthesis 10.

Ideally, the pores or apertures in the semi-permeable membrane should be about 10 microns non-expanded to about 20 microns expanded, while the dialysis molecule should have a nominal size in the range of 50 to 100 microns. Of course, these numerical values are disclosed for purposes of illustration only, and are not intended to limit the scope of the present invention.

The semi-permeable membrane can be made of any suitable synthetic plastic material, such as a Gortex-like cloth, and the dialysate can be made from a wide variety of molecules or microstructures well-known to those skilled in the art. The thoracic pouch 16, first conduit 26, second conduit 36 and impermeable outer wall 58 of the abdominal sac 12 are preferably made from silicon plastic, which is inert and does not cause peritoneal irritation.

In the preferred form of this invention, the dialysis sac 32 is positioned between the peritoneum and mesenteric parieties in the left lower quadrant of the abdomen to extract fluids (unconcentrated urine) via osmotic diffusion and ultra filtration by the same physiological principles that control regular peritoneal dialysis. The dialysis sac 32 swells with unconcentrated urine which then traverses the window 34 shared with the abdominal sac 12. As shown in Fig. 1, the dialysate does not leave the dialysis sac 32 and therefore cannot be absorbed by the lymphatic system or irritate the peritoneum. The

unconcentrated urine entering the dialysis sac 32 through the semi-permeable membrane and exiting through the window 34 will then be directed through the first conduit 26 and the one-way valve 28, through the diaphragm 14 and into the thoracic pouch 16 by the internal body pumping mechanism based on relative pressure changes in the abdomen and thorax during the breathing cycle, as described later in this application. It should be understood that neither the conduit 26 nor the thoracic pouch 16 have any permeability, *i.e.*, they are impermeable so as to preclude the escape of any unconcentrated urine therefrom.

As is shown in Fig. 1, the abdominal sac 12 and the thoracic pouch 16 communicate with subcutaneous access reservoirs 50 and 51, respectively, each of which include an access section closely adjacent the patient's skin. The subcutaneous access reservoirs (SARs) 50 and 51, permit the monitoring and testing of the urine in order to determine the effectiveness of the prosthesis. The subcutaneous access reservoirs 50 and 51 provide adjustments of urine flow and urine constituents by adding or subtracting dialysate to fit each patient's needs. The dialysate can be added or withdrawn from the subcutaneous access reservoirs 50 and 51 using a syringe or tube inserted through the patient's skin into the reservoirs.

The unconcentrated urine within the thoracic pouch 16 then passes through the second conduit 36 and one-way valve 38 therein to a section of the patient's bowel 18. Movement of the unconcentrated urine from the thoracic pouch 16 through the second conduit 36 takes place by an internal pumping mechanism to be described in greater detail

hereinafter. Suffice it to state at this time that the second conduit 36 traverses a relatively long segment of bowel that has been isolated from the rest of the bowel. The segment that preferably is selected includes the right colon and ileum, and is capable of 90% water reabsorption in the bowel, which translates to 10 to 20 liters of water per day.

The movement of the unconcentrated urine through the bowel 18 is a unique feature of the present invention. The second conduit 36, which directs the unconcentrated urine into the segment of the patient's bowel 18 includes a series of relatively large holes (or apertures) 54, *e.g.*, one-half cm, so as to allow the unconcentrated urine within the conduit 36 to move into the bowel 18, wherein the bowel 18 functions to reabsorb water, electrolytes and small molecules, resulting in the formation of concentrated urine. The bowel will not absorb large molecules, standard excretory wastes and other poisons, or even standard proteins. It should be noted that the jejunum is anastomosed to transverse colon to restore the integrity of the GI tract, and therefore, though the section patient's bowel 18 is isolated, its blood supply remains intact so as to permit it to function in this invention.

Some of the concentrated urine will traverse the appendix 22, which has a one-way peristalsis to the bladder 20, which appropriately excretes the concentrated urine based on the bladder's normal function. The remaining urine is returned through the distal end 46 of the conduit 36 to the abdominal sac 12 for recirculation and recleansing. This distal end 46 of the conduit 36 is impermeable to preclude the escape of any urine therefrom.

It is important to note that in this exemplary prosthesis of this preferred embodiment, there is no free dialysate in the peritoneal cavity; the dialysate being retained in the dialysate sac 32. It is only in such a system that it is both safe and advantageous for there to be emphatic reabsorption.

In fact, it should be noted that in prior art peritoneal dialysis the reabsorption of dialysate and unconcentrated urine creates a major problem for two reasons. First, it interferes with the vary process of discarding this excessive fluid. Second, any system in which dialysate is reabsorbed causes two other problems, the first of which is that it interferes with the very difference in osmotic pressure needed for the whole process of diffusion and ultra filtration, and secondarily, even if the dialysate molecule is inert versus the sugar, salt or albumin used in standard dialysis, each of which causes its own special problems when reabsorbed by the lymphatic system, it creates a tremendous problem with oncotic pressure.

Therefore, it should be emphasized that the continuous internal peritoneal dialysis prosthesis and method of this preferred embodiment is highly advantageous because the dialysate itself is separate at all times from the peritoneal space and from lymphatic absorption. The fact that some partially concentrated urine is recycled in the present invention is also advantageous. In particular, this recycling of partially concentrated urine allows for further cleansing of nitrogenous wastes from the urine and is precisely the same thing that happens during urine formation in a kidney that is functioning normally.

It also should be noted that, in a manner identical to the functioning of a normal kidney, the lower the serum osmolality (the more liquids a patient consumes) the better the peritoneal system of this invention works. In particular, the greater the differential between the osmotic pressure in the dialysis sac 32 employed in this invention and the blood (serum osmolality) the more urine is made. Therefore, the patient employing the prosthesis of this invention is able to drink as much as he or she wants, unlike other dialysis patients, because his/her increased intake of water simply increases the performance of the prosthesis of this invention. This is a significant benefit of the present invention.

As noted earlier, when the unconcentrated urine is turned into concentrated urine within the section of the patient's bowel 18, most of the concentrated urine will exit to the distal right ureter 24, which can be attached to the cecum or appendix 22 when appropriate, and this concentrated urine, of course, would then go into the urinary bladder 20 to be expelled intermittently, just as in a normally functioning human patient.

It should be noted that the process is continuous and prevents sudden changes in volume and concentration of the blood's constituents. The continuous operation of the prosthesis of this invention relies upon the internal body pumping action of the disclosed system. This internal body pumping action is a variation of the internal body pump and systems disclosed in Applicant's U.S. Patent No. 5,813,410. The entire subject matter of this latter patent is hereby incorporated by reference herein.

However, by way of explanation, the fluid is circulated through the prosthesis 10 of this invention by means of a body-operated pump, *e.g.*, the abdominal sac 12 and thoracic pouch 16 serve as pumps operated by a patient's breathing pattern to cause the fluid to flow through the prosthesis. In particular, fluid flow within the prosthesis 10 is created by taking advantage of the normal function of a person's diaphragm 14 and the normal internal pressure relationships that exist between the thoracic cavity and the abdominal cavity of the person's body while a person is breathing. Specifically, during inspiration (inhaling) the diaphragm, which separates the thoracic and abdominal cavities, is forced to descend; thereby leading to an increase in the intra thoracic volume and a corresponding decrease in the intra thoracic pressure. Conversely, the volume of the abdominal cavity decreases and the pressure in that cavity increases. This action forces fluid from the abdominal sac 12 located in the abdominal cavity through conduit 26 and into the thoracic pouch 16 in the thoracic cavity. The flow from the abdominal sac 12 to the thoracic pouch 16 is limited to flowing through the conduit 26 only in the direction of arrow 30, due to the arrangement of the one-way valve 28 in that conduit 26.

Upon expiration (exhaling) the operation of the diaphragm is reversed. That is, the diaphragm is forced to rise; thereby leading to a decrease in the intra thoracic volume and the corresponding increase in the intra thoracic pressure. Conversely, during expiration, the volume of the abdominal cavity increases and the pressure in that cavity decreases. This action forces fluid from the thoracic pouch 16, located in the thoracic cavity, preferably in the costo phrenic sulcus thereof, to flow through the conduit 36, and into the

section of the patient's bowel 18 for delivery into the urinary bladder 20 or back into the abdominal sac 12. Fluid flow from the thoracic pouch 16 through the bowel section 18 is limited to flowing only in the direction of arrow 40, due to the inclusion of the one-way valve 38 in the second conduit 36. Likewise, fluid flow from the bowel section 18 to the abdominal sac 12 is limited to flowing only in the direction of arrow 49, due to the inclusion of the one-way valve 48.

As should be appreciated from the foregoing, in operation the unconcentrated urine which is directed into the dialysis sac 32 is continuously moved through the prosthesis 10 by the breathing cycle of a patient, as described. The unconcentrated urine directed through the second conduit 36 into the bowel section 18 is then processed by the bowel section to concentrate the urine for ultimate removal through the urinary bladder 20.

If necessary, or desired, the pumping action provided by the breathing cycle of the patient can be augmented, or even supplanted, by another device, *e.g.*, a mechanical or electrical pump implanted in the person's body in fluid communication with the loop of circulating fluid.

Referring to Fig. 2, there is shown at 62, an exemplary continuous internal peritoneal dialysis prosthesis inserted within a patient's body in accordance with a second preferred embodiment of this invention, which is similar to the prosthesis 10 discussed above and illustrated in Fig. 1. As shown in Fig. 2, the prosthesis 62 includes an abdominal sac 64 in the abdominal region of the patient below diaphragm 14, a thoracic pouch 16 in the thoracic region of the patient's body above the diaphragm 14, a section

of the patient's bowel 18 located within the abdominal section of the patient, and the patient's urinary bladder 20 connected to a downstream end of the bowel 18 through the patient's cecum or appendix 22 and distal right ureter 24. The abdominal sac 64 is connected to the thoracic pouch 16 through a conduit 26, including a one-way valve 28 therein. The one-way valve 28 permits fluid to flow only in the direction of arrow 30 from the abdominal sac 64 into the thoracic pouch 16.

The prosthesis 62 includes a second conduit 36 having a proximal end 68 and a distal end 46. This second conduit 36 is connected to the thoracic pouch 16 through its proximal end 68 and passes through the diaphragm 14 into and through a section of the patient's bowel 18. The second conduit includes a one-way valve 38 at its proximal end 68 to permit the unconcentrated urine to flow from the thoracic pouch 16 through the section of the patient's bowel 18 only in the direction of arrow 40. The distal end 46 of the second conduit 36 extends through a lower end of the bowel 18 and is connected to the abdominal sac 64 to recycle the flow of unconcentrated (or partially concentrated) urine back into the abdominal sac 64. The distal end 46 is provided with a one-way valve 48 to permit the urine to flow only in the direction of arrow 49 from the patient's bowel 18 to the abdominal sac 64. The patient's bowel 18 is sutured to the conduit 36 at both the entrance 42 to the bowel 18 and the exit 44 from the bowel 18.

As noted above, the prosthesis 62 shown in Fig. 2 is constructed similar to the prosthesis 10 shown in Fig. 1. However, in this embodiment, the dialysate is not contained only within a dialysis sac. In fact, the abdominal sac 64 does not include or

share a window with a dialysis sac. In Fig. 2, the abdominal sac 64, thoracic pouch 16 and conduits 26 and 36 provide a closed system for the dialysate, allowing the dialysate to cycle within the prosthesis 62, but preventing the dialysate from leaving the prosthesis 62.

The abdominal sac 64 is generally formed of a semi-permeable membrane having a porosity which precludes the dialysate within the abdominal sac 64 from escaping into the peritoneal region, but still permits unconcentrated urine within the peritoneal region to enter the abdominal sac 64 through osmotic pressure. Because the abdominal sac 64 is required to function in an aqueous environment, it preferably is formed of a synthetic plastic material with some elastic qualities (*e.g.*, Gortex-like cloth). However, the abdominal sac 64 should not be so elastic as to expand to an extent that permits the dialysate molecules or microstructures to exit from expanded pores of its walls.

The abdominal sac 64 may be similar to the abdominal sac 12 shown in Fig. 1, but without the wall 34. As with the abdominal sac 12 of Fig. 1, portions of the wall of the abdominal sac 64 may alternatively be formed of an impermeable or substantially impermeable membrane that is more elastic than the semi-permeable membrane and does not permit the dialysate to exit, even when the impermeable or substantially impermeable membrane is expanded beyond its elastic limit. Therefore, before the semi-permeable membrane expands under pressure to an extent that could permit dialysate to exit, the impermeable or substantially impermeable membrane stretches to contain the dialysate while inhibiting the dialysate from exiting therefrom.

As noted earlier, the section of the patient's bowel 18 is sutured to the conduit 36 at both the entrance 42 to the bowel 18 and the exit 44 from the bowel 18, thereby enclosing a central region 66 of the conduit 36. This central section 66 includes a semi-permeable wall so as to allow the unconcentrated urine within the central region of the second conduit 36 to move into the bowel 18, wherein the bowel functions to reabsorb water, electrolytes and small molecules, resulting in concentrated urine. However, the semi-permeable wall prevents the dialysate from moving into the bowel, thus keeping the dialysate within the prosthesis 62. It should be understood that neither the conduit 26, the thoracic pouch 16, nor the proximal end 68 of the conduit 36 have any permeability, *i.e.*, they are impermeable so as to preclude the escape of any unconcentrated urine or dialysate therefrom.

As is shown in Fig. 2, the unconcentrated urine entering the abdominal sac 64 through the semi-permeable membrane, and the dialysate are directed through the first conduit 26 and the one-way valve 28, through the diaphragm 14 and into the thoracic pouch 16 by the internal body pumping mechanism described above. The unconcentrated urine and dialysate within the thoracic pouch 16 then pass through the second conduit 36 and one-way valve 38 therein to a section of the patient's bowel 18. Movement of the unconcentrated urine and dialysate from the thoracic pouch 16 through the second conduit 36 takes place by the internal body pumping mechanism described above. As mentioned above, the central region 66 of the second conduit 36, which directs the unconcentrated urine and dialysate into the segment of the patient's bowel 18 is formed of a semi-

permeable membrane so as to allow the unconcentrated urine within the conduit 36 to move into the bowel, wherein the bowel functions to reabsorb water, electrolytes and small molecules, resulting in concentrated urine. However, the semi-permeable membrane prevents the dialysate from leaving the second conduit 36.

In a manner similar to the prosthesis shown in Fig. 1, some of the concentrated urine in Fig. 2 will traverse the appendix 22, which has a one-way peristalsis to the bladder 20, which appropriately excretes the concentrated urine based on the bladder's normal function. The remaining urine (unconcentrated and partially concentrated) is returned with the dialysate through the distal end 46 of the conduit 36 to the abdominal sac 64 for circulating and recleansing. Preferably, the distal end 46 of the conduit 36 is impermeable to preclude the escape of any urine and dialysate therefrom.

Typically in chronic peritoneal dialysis, the dialysate is introduced directly into the peritoneal space via a catheter and removed after it has drawn in urine. Introducing the dialysate into the peritoneal space presents problem with the chronic peritoneal dialysis procedure. Peritoneal irritation and chronic thickening caused by the dialysis leads to poor diffusion and ultra filtration. In addition, the dialysate in the peritoneal space can cause problems in the bloodstream (*e.g.*, hypertonic sugar, hypertonic salt, increases in nitrogenous wastes, and problems in the bloodstream including bleeding and clotting disorders, poisoning various enzyme systems, antigen-antibody reactions, D-C, etc.).

The embodiments of the invention discussed above and illustrated in Figs. 1 and 2 do not suffer from these problems because the dialysate cannot filter through the semi-

permeable membrane. However, the embodiments of the invention discussed below allow for direct contact of the dialysate with the peritoneum. The continuous internal peritoneal dialysis prosthesis discussed below are of greater benefit when using a dialysate that cannot be absorbed by the lymphatic system or where there is minimal absorption of the dialysate without toxicity.

Referring to Fig. 3, an exemplary continuous internal peritoneal dialysis prosthesis inserted within a patient's body is schematically illustrated at 70. The prosthesis 70 includes an abdominal sac 64 in the abdominal region of the patient below the diaphragm 14, a thoracic pouch 16 in the thoracic region of the patient's body above the diaphragm 14, a section of a patient's bowel 18 located within the abdominal region, conduits 26 and 36 connected between the abdominal sac 64 and the thoracic pouch 16, and a semi-permeable membrane 72 enclosed within the bowel 18. The abdominal sac 64, thoracic pouch 16, bowel 18, and conduits 26 and 36 are similar to the like elements shown in Fig. 2. However, the conduits 26 and 36 include a series of relatively large holes 54 (*e.g.*, one-half centimeter) that allow urine and dialysate to permeate therethrough, as will be described later.

The abdominal sac 64 may be similar to the abdominal sac 12 shown in Fig. 1, but without the wall 34. As with the abdominal sac 12 of Fig. 1, portions of the abdominal sac 64 may alternatively be formed of an impermeable or substantially impermeable membrane that is more elastic than the semi-permeable membrane and does not permit the dialysate to exit, even when the impermeable or substantially impermeable membrane

is expanded beyond its elastic limit. Therefore, before the semi-permeable membrane expands under pressure to an extent that could permit dialysate to exit, the impermeable or substantially impermeable membrane stretches to contain the dialysate while inhibiting the dialysate from exiting therefrom.

As can be seen in Fig. 3, the section of the patient's bowel 18 is sutured to the conduit 36 at both the entrance 42 to the bowel 18 and the exit 44 from the bowel 18. The semi-permeable membrane 72 extends about the second conduit 36 within the bowel 18 and is attached to the second conduit 36 at both the entrance 74 to the membrane 72 and the exit 76 from the membrane 72. The semi-permeable membrane 72 is preferably a synthetic plastic material with some elastic qualities having a porosity which precludes dialysate from filtering through the semi-permeable membrane, but permits unconcentrated urine to filter through the material.

In this embodiment, both the dialysate and unconcentrated urine are present in the peritoneal region. The abdominal sac 64 receives unconcentrated urine and dialysate via the relatively large holes 54 of the first conduit 26. In addition, the abdominal sac 64 receives unconcentrated urine through sections of the wall of the abdominal sac 64 that are made of semi-permeable membrane.

The unconcentrated urine and dialysate entering the abdominal sac 64 is directed through the first conduit 26 and the one-way valve 28, through the diaphragm 14 and into the thoracic pouch 16 by the internal body pumping mechanism described above. Unconcentrated urine and dialysate also flow from the peritoneum through the relatively

large holes 54 into the first conduit 26, and is directed toward the thoracic pouch 16. The unconcentrated urine and dialysate within the thoracic pouch 16 then pass through the second conduit 36 and the one-way valve 38 therein to a section of the patient's bowel 18. Movement of the unconcentrated urine and dialysate from the thoracic pouch 16 through the second conduit 36 takes place by the internal pumping mechanism described above, which may be assisted or supplemented with a pump. As noted above, the second conduit 36 which directs the unconcentrated urine and dialysate into the segment of the patient's bowel 18 includes a series of relatively large holes 54 so as to allow the unconcentrated urine and dialysate within the second conduit 36 to flow out of the conduit 36. The semi-permeable membrane 72 that is within the bowel 18 has a porosity which precludes the dialysate that filtered through the holes 54 of the second conduit 36 from escaping into the bowel 18, but still permits the unconcentrated urine to permeate into the bowel 18, wherein the bowel 18 functions to reabsorb water, electrolytes and small molecules resulting in concentrated urine.

As noted earlier, when the unconcentrated urine is turned into concentrated urine within the section of the patient's bowel 18, most of the concentrated urine will exit to the distal right ureter 24, which can be attached to the cecum or appendix 22 when appropriate. The concentrated urine will then flow into the urinary bladder 20 to be expelled intermittently, just as in a normally functioning human patient. The dialysate and returning urine is returned through the distal end 46 of the conduit 36 to the abdominal sac 64 for recirculation and recycling. This distal end 46 of the conduit 36,

and the sections of the conduits 26 and 36 above the diaphragm 14 are impermeable to preclude the escape of any urine or dialysate therefrom.

Fig. 4 is still another embodiment of the invention wherein dialysate is in direct contact with the peritoneum. Referring to Fig. 4, an exemplary continuous internal peritoneal dialysis prosthesis inserted within a patient's body is schematically illustrated at 80 and is similar to the prosthesis is shown in Fig. 1. The prosthesis 80 includes an abdominal sac 82 in the abdominal region of the patient below diaphragm 14, a thoracic pouch 16 in the thoracic region of the patient's body above the diaphragm 14, a section of the patient's bowel 18 located within the abdominal section of the patient and a urinary bladder 20 connected to a downstream end of the bowel 18 through the patient's cecum or appendix 22 and distal right ureter 24.

The abdominal sac 82 includes a semi-permeable outer wall 56 and an impermeable outer wall 58 separated by a semi-permeable window 86. The region of the abdominal sac 82 defined by the semi-permeable outer wall 56 and the semi-permeable window 86 is a dialysis sac 84. The semi-permeable outer wall 84 and window 86 are formed of a semi-permeable membrane as discussed in detail above. The abdominal sac 82, dialysis sac 84, thoracic pouch 16, first conduit 26, bowel 18 and second conduit 36 shown in Fig. 4 are substantially similar to the abdominal sac 12, dialysis sac 32, thoracic pouch 16, first conduit 26, bowel 18 and second conduit 36 shown in Fig. 1. However, instead of the distal end 46 of the second conduit 36 being formed of an impermeable material and connected to the abdominal pouch 12 (Fig. 1), the distal end 46 of Fig. 4

includes a series of relatively large holes 54 (*e.g.*, one-half centimeter) and is connected to the semi-permeable outer wall 56 of the dialysis sac 84.

The distal end 46 includes the holes 54 so as to allow unconcentrated urine and dialysate in the peritoneum to move into the conduit 36 and then into the dialysis sac 84. The dialysate is contained within the distal end 46 of the conduit 36 and the dialysis sac 84 and does not flow through the remainder of the prosthesis 80. The one-way valve 48 permits the unconcentrated and partially concentrated urine exiting from the second conduit 36 in the bowel 18 to travel towards the dialysis sac 84, but does not allow fluid, including the dialysate, to enter the second conduit 36 in the bowel 18 from the distal end 46.

In Fig. 4, unconcentrated urine flows from the abdominal sac 82 through the first conduit 26 and one-way valve 28 through the diaphragm 14 to the thoracic pouch 16. The unconcentrated urine within the thoracic pouch 16 then passes through the diaphragm 14 and one-way valve 38 in the second conduit to the patient's bowel 18. Movement of the urine through the prosthesis 10 takes place by the internal pumping mechanism described in detail above.

As noted earlier during the discussion of Fig. 1, the second conduit 36 of Fig. 4, which directs the unconcentrated urine into the segment of the patient's bowel 18, includes a series of relatively large holes 54. The holes 54 allow the unconcentrated urine within the conduit 36 to move into the bowel 18, wherein the bowel 18 functions to reabsorb water, electrolytes and small molecules resulting in concentrated urine. Some

of the concentrated urine will traverse the appendix 22 which has a one-way peristalsis to the bladder 20, which appropriately excretes the concentrated urine based on the bladder's normal function. The remaining urine is returned through the distal end 46 of the conduit 36 (where it is mixed with unconcentrated urine and dialysate from the peritoneum) to the dialysis sac 84 for recirculation and recleansing.

In order to prevent the dialysis sac 84 from expanding to an extent that permits the dialysate to exit the walls, portions of the semi-permeable outer wall 56 and the semi-permeable window 86 may alternatively be formed of an impermeable or substantially impermeable membrane that is more elastic than the semi-permeable membrane and does not permit the dialysate to exit, even when the impermeable or substantially impermeable membrane is expanded beyond its elastic limit. Therefore, before the semi-permeable membrane expands under pressure to an extent that could permit dialysate to exit, the impermeable or substantially impermeable membrane stretches to contain the dialysate while inhibiting the dialysate from exiting therefrom. Also, the impermeable wall 58 could be made elastic and the semi-permeable wall 56 and window 86 made inelastic.

Although the conduits 26 and 36 are illustrated in the exemplary embodiments shown in Figs. 1-4 as being separate conduits spaced apart from each other and extending through separate passages in the diaphragm 14, it should be understood that, in a preferred construction, the conduits 26 and 36 are interconnected together and pass through only a single aperture in the diaphragm 14. The spaced apart arrangement of the conduits 26 and 36 is shown in the drawings for purposes of clarity.

The operation of all of the embodied prostheses shown in Figs. 1-4 is preferably continuous and relies upon the internal body pumping action of the disclosed systems. This internal body pumping action is described in relation to Fig. 1 and is substantially similar in operation for the other exemplary embodiments shown in Figs. 2-4 as a skilled artesian would readily understand. The described internal body pumping action is a variation of the internal body pump and systems disclosed in Applicant's U.S. Patent No. 5,813,410, the entire subject matter of which is incorporated by reference herein. In addition, for all of the exemplary embodiments, the pumping action provided by the breathing cycle of the patient can be augmented, or even supplanted, by another device (*e.g.*, a mechanical or electrical pump implanted in the person's body in fluid communication with the loop of circulating fluid).

Referring to Fig. 5, a further and preferred exemplary continuous peritoneal dialysis prosthesis inserted within a person's body is schematically illustrated at 100. The prosthesis 100 includes a thoracic pouch 16 in the thoracic region of the patient's body above the diaphragm 14, a section of the patient's bowel 18 located within the abdominal region, conduits 26 and 36 communicating between the thoracic pouch 16 and the abdominal region, and a semi-permeable membrane 72 enclosed within the bowel 18. The thoracic pouch 16, bowel 18, and conduits 26 and 36 are similar to the like elements shown in Fig. 3. However, this embodiment is different than the embodiment shown in Fig. 3 because this embodiment omits the abdominal sac disclosed in Fig. 3.

As can be seen in Fig. 5, the section of the patient's bowel 18 is sutured to the conduit 36 at both the entrance 42 to the bowel 18 and the exit 44 from the bowel 18. The semi-permeable membrane 72 extends about the second conduit 36 within the bowel 18 and is attached to the second conduit 36 at both the entrance 74 to the membrane 72 and the exit 76 from the membrane 72. The semi-permeable membrane 72 is preferably a synthetic plastic material with some elastic qualities having a porosity which precludes dialysate from filtering through the semi-permeable membrane, but permits unconcentrated urine to filter through the material. The conduits 26 and 36 include a series of relatively large holes 54 (*e.g.*, about one-half centimeter) that allow urine and dialysate to permeate therethrough as will described later.

In this embodiment, both the dialysate and unconcentrated urine are present in the peritoneal region. The first conduit receives unconcentrated urine and dialysate via the relatively large holes 54 and distal opening 102. The unconcentrated urine and dialysate is directed through the first conduit 26 and the one-way valve 28, through the diaphragm 14 and into the thoracic pouch 16 by the internal body pumping mechanism described above. The unconcentrated urine and dialysate within the thoracic pouch 16 then pass through the second conduit 36 and the one-way valve 38 therein to a section of the patient's bowel 18. Movement of the unconcentrated urine and dialysate from the thoracic pouch 16 through the second conduit 36 takes place by the internal pumping mechanism described above, which may be assisted or supplemented with a pump. In

particular, the thoracic pump 16 serves as a pump influenced by a patient's breathing pattern to cause the unconcentrated urine and dialysate to flow through the prosthesis 100.

The prosthesis 100 omits the abdominal sac disclosed in the other embodiments of this invention and generally employs the peritoneal region as the "sac" region for retaining dialysate and unconcentrated urine. Accordingly, like the prosthesis shown above in Figs. 3 and 4, the prosthesis 100 is of greatest benefit when using a dialysate that cannot be absorbed by the lymphatic system or where there is minimal absorption of the dialysate without toxicity (*e.g.*, absorbable albumin). Because the dialysate is not contained within a separate abdominal sac, it is preferred that dialysate is added to the prosthesis (*e.g.*, about 1 liter every few days) to ensure that a sufficient amount of dialysate is retained within the peritoneal region.

It should be apparent that the unconcentrated urine and dialysate does not flow through the prosthesis 100 as efficiently as the fluids flow through the embodiments discussed above that include both an abdominal sac and a thoracic pouch. Without an abdominal sac, the prosthesis does not form a closed loop and the thoracic pouch is relied upon to cause the fluid to flow through the prosthesis without the aid of an abdominal sac, as described above. Accordingly, this embodiment may be better suited for a patient that has only partial kidney failure.

As noted above, the second conduit 36 which directs the unconcentrated urine and dialysate into a segment of the patient's bowel 18 includes a series of relatively large holes 54 so as to allow the unconcentrated urine and dialysate within the second conduit

36 to flow out of the conduit. The semi-permeable membrane 72 that is within the bowel has a porosity which precludes the dialysate that filters through the holes 54 of the second conduit 36 from escaping into the bowel 18, but still permits the unconcentrated urine to permeate into the bowel 18, wherein the bowel functions to reabsorb water, electrolytes and small molecules resulting in concentrated urine.

Still referring to Fig. 5, it should be noted that in lieu of the relatively large holes 54 located in the second conduit 36 and the semi-permeable membrane 72 located within the bowel 18, the conduit 36 within the bowel 18 can be constructed like the central region 66 of the conduit 36 shown in Fig. 2. That is, in Fig. 5, the conduit 36 within the bowel 18 can be formed of the semi-permeable membrane.

As noted earlier, when the unconcentrated urine is turned into concentrated urine within the section of the patient's bowel 18, most of the concentrated urine will exit to the distal right ureter 24 which can be attached to the cecum or appendix 22 when appropriate. The concentrated urine will then flow into the urinary bladder 20 to be expelled intermediately, just as in a normally functioning human person. The dialysate and returning urine is returned through the distal end 46 of the conduit 36 into the abdominal region. Preferably, the distal end 46 of the second conduit 36 should either be of a very small diameter, or employ a moderate pressure one-way valve 48 therein to control the flow of fluid into the peritoneal space in a manner that allows adequate time for the bowel to absorb water from the unconcentrated urine passing therethrough, but not

such as to prevent flow of unconcentrated or partially concentrated urine back into the peritoneal space for lymphatic reabsorption and recycling through the entire system.

It should be noted that the thoracic pouch 16 preferably communicates with a subcutaneous access reservoir 50, which includes an access section closely adjacent the patient's skin. The subcutaneous access reservoir 50 permits the monitoring and testing of the urine in order to determine the effectiveness of the prosthesis. The reservoir 50 also provides adjustments of urine flow and urine constituent by adding or subtracting dialysate to fit each patient's needs. The dialysate can be added or withdrawn from the subcutaneous access reservoir 50 using a syringe or tube inserted through the patient's skin into the reservoir.

Referring to Fig. 6, there is shown at 110 an exemplary internal peritoneal dialysis prosthesis inserted within a patient's body in accordance with yet still another preferred embodiment of this invention. As shown in Fig. 6, the prosthesis 110 includes an abdominal sac 112 in the abdominal region of the patient below the diaphragm. The abdominal sac 112 includes an extension that expands into a section of the patient's bowel 18.

The abdominal sac 112 may be similar to the abdominal sacs discussed above. For example, the abdominal sac is arranged for having a dialysate therein. This sac 112 is generally formed of a semi-permeable membrane having a porosity which precludes the dialysate within the abdominal sac 112 from escaping into the peritoneal region but still permits unconcentrated urine within the peritoneal region to enter the abdominal sac 112

through osmotic pressure. Because the abdominal sac 112 is required to function in an aqueous environment, it preferably is formed of a synthetic plastic material with some elastic qualities (*e.g.*, Gortex-like cloth). However, the abdominal sac 112 should not be so elastic as to expand to an extent that permits the dialysate molecules or microstructures to exit from expanded pores of its walls.

As with the abdominal sacs discussed above, portions of the wall of the abdominal sacs 112 may alternatively be formed of an impermeable or substantially impermeable membrane that is more elastic than the semi-permeable membrane and does not permit the dialysate to exit, even when the impermeable or substantially impermeable membrane is expanded beyond its elastic limit. Therefore, before the semi-permeable membrane expands under pressure to an extent that could permit dialysate to exit, the impermeable or substantially impermeable membrane stretches to contain the dialysate while inhibiting the dialysate from exiting therefrom.

Still referring to Fig. 6, a section of the patient's bowel 18 is sutured to the abdominal sac 112, thereby enclosing the extension 114 of the sac in the bowel. This extension includes the semi-permeable membrane wall so as to allow the unconcentrated urine drawn into the abdominal sac 112 by osmotic pressure to move into the bowel 18, wherein the bowel functions to reabsorb water, electrolytes and small molecules, resulting in concentrated urine. However, the semi-permeable membrane wall prevents the dialysate from moving into the bowel, thus keeping the dialysate within the abdominal sac 112.

The abdominal sac 112 preferably communicates with a subcutaneous access reservoir 51, which includes an access section closely adjacent the patient's skin. The subcutaneous access reservoir (SAR) 51 permits the monitoring and testing of the dialysate and urine in order to determine the effectiveness of the prosthesis. The SAR 51 provides adjustment of urine flow and urine constituents by adding or subtracting dialysate to fit each patient's needs. The dialysate can be added or withdrawn from the SAR 51 using a syringe or tube inserted through the patient's skin into the reservoir.

Unlike the other embodiments of the invention discussed above, the prosthesis 110 does not include conduits for continuous mixing and circulation of unconcentrated urine and dialysate. In this regard, it should be noted that the prosthesis 110 is likely not as efficient as the other preferred embodiments because this prosthesis 110 does not take advantage of a respiratory pump. Accordingly, this prosthesis is better suited for patients having a less severe renal failure. Another possible disadvantage of this embodiment is that the abdominal sac 112 may be subject to layering and stagnation of dialysate and receive unconcentrated urine making the patient more susceptible to infection. In other words, the mixing and circulation provided by the prosthesis of the embodiments discussed above improves the efficiency of the dialysis and precludes layering and stagnation of fluids within the prosthesis. The possible layering and stagnation of the fluids may be minimized in this embodiment if the patient frequently moves or changes the angular orientation (*e.g.*, vertical, horizontal) of their torso, to allow the fluids in the abdominal sac 112 to flow influenced by gravitational pull. However, one advantage of

this prosthesis over the embodiments described above, is that this prosthesis 110 uses fewer elements and is more simple in its operation. This prosthesis 110 also creates less strain on the patient during surgery to implant the prosthesis than the prosthesis of other preferred embodiments since fewer elements are inserted into the body.

Referring to Fig. 7, there is shown at 120, an exemplary continuous internal peritoneal dialysis prosthesis inserted within a patient's body in accordance with yet another preferred embodiment of this invention. The prosthesis 120 is similar to the prosthesis discussed above in Figures 1-6, and particularly in Figs. 1-4. As shown in Fig. 7, the prosthesis 120 includes an abdominal sac 64 in the abdominal region of the patient below diaphragm 14, a thoracic pouch 16 in the thoracic region of the patient's body above the diaphragm 14, first and second conduits 26, 36 arranged for communicating fluid between the abdominal sac 64 and the thoracic pouch 16, and a section of the patient's bowel 18 located within the abdominal section of the patient. The patient's urinary bladder 20 is connected to a downstream end of the bowel 18 preferably via the patient's distal right ureter 24 and the patient's cecum or appendix 22.

The abdominal sac 64 is connected to the thoracic pouch 16 through the conduit 26, which preferably includes a one-way valve 28 therein. The one-way valve 28 permits fluid to flow only in the direction of arrow 30 from the abdominal sac 64 into the thoracic pouch 16.

The second conduit 36 is connected to the thoracic pouch 16 through a proximate end 122 and passes through the diaphragm 14 into and through the section of the patient's

bowel 18, which has been separated from the digestive system (or GI tract) of the patient. While not being limited to a particular theory, the second conduit 36 includes a one-way valve 38 near its proximal end 122 to permit fluid (*e.g.* dialysate and urine) to flow from the thorascic pouch 16 through the section of the patient's bowel 18 only in the direction of arrow 40.

As can best be seen in Fig. 7, the second conduit 36 has a Y-shaped tubing that bifurcates into two conduit sections 124 and 126. First conduit section 124 includes a distal opening 130, and extends from the second conduit 36 into a first segment 128 of the bowel 18 until it ends at the distal opening 130. The second conduit section 126 extends through a second segment 132 of the bowel 18 and has a distal end 134 connected to the abdominal sac 64 to recycle the flow of dialysate (and possibly some urine) back into the abdominal sac 64, as will be described in greater detail below. While not being limited to a particular theory, the second conduit section 126 is provided with a one-way valve 48 at its distal end 134 to permit the fluid (*e.g.*, dialysate and urine) to flow only in the direction of arrow 49 from the patient's bowel 18 to the abdominal sac 64.

The first bowel segment 128 is sutured to the first conduit section 124 at the entrance 42 to the first bowel segment. The second bowel segment 132 is sutured to the second conduit section 126 at an entrance 136 to the second bowel segment and at an exit 44 from the bowel 18.

The conduit sections 124, 126 have apertures 54 that are arranged to communicate within the bowel segments 128,132 so as to allow the unconcentrated urine and dialysate

within the second conduit 36 to move into the bowel 18. The bowel 18 functions to reabsorb water, electrolytes and small molecules, resulting in the formation of concentrated urine. As noted above, the section of bowel 18 is isolated from the rest of the bowel, and therefore from the Gastrointestinal (GI) tract. While not being limited to a particular theory, the section of bowel 18 that is selected preferably includes the right colon as the first bowel segment 128 and the ileum as the second bowel segment 132. As noted above, the section of bowel 18 is capable of about 90% water reabsorption which translates to 10 to 20 liters of water per day.

Still referring to Fig. 7, a filter 138 is positioned at a lower end 140 of the section of bowel 18. The filter 138 is a semi-permeable membrane that allows urine to pass through but blocks the dialysate from filtering through the membrane. While not being limited to a particular theory, the filter 138 is preferably disk-shaped and supported at its periphery by a plastic frame. The filter 138 is preferably held in place in the section of bowel 18 with an elastic member (*e.g.*, rubber band) wrapped around the lower section 140 of the bowel 18 and the plastic frame. If desired, the plastic frame may include a groove or notch around its frame to assist in holding the filter 138 and elastic member in position within the bowel 18.

The filter 138 functions similarly to the semi-permeable membrane 72 discussed above and shown in Fig. 3. As such, the semi-permeable membrane filter 138 is preferably a synthetic plastic material with some elastic quality having a porosity which precludes dialysate from filtering through the semi-permeable membrane, but permits

urine to filter through the material. The filter 138 provides an alternate approach to the structure shown in Fig. 3 for filtering urine, but not dialysate, to the appendix 22, which has a one-way peristalysis to the bladder 20. As in the other embodiments, the bladder 20 appropriately excretes the concentrated urine based on the bladder's normal function.

Referring to Fig. 7, the urine remaining in the section of bowel 18 that is not filtered through the semi-permeable filter 138 is returned through the distal end 134 of the second conduit section 126 to the abdominal sac 64 for recirculation. While not being limited to a particular theory, the distal end 134 of the second conduit section 126 is preferably impermeable to preclude the escape of any urine therefrom.

The second conduit, its extension (the first conduit section 124), and the filter 138 form a fluid guide member 142 that is adapted to transfer unconcentrated urine from the thoracic pouch 16 via the second conduit into the separate section of bowel 18, and to transfer dialysate from the thoracic pouch to the abdominal sac 64.

As noted above, the prosthesis 120 shown in Fig. 7 is constructed similarly to the various prostheses discussed above. In this embodiment, the dialysate is not contained within a dialysis sac. While not being limited to a particular theory, the abdominal sac 64 preferably does not include or share a window with a dialysis sac, as shown, for example, in Figs. 1 and 4. In Fig. 7, the abdominal sac 64, thoracic pouch 16, conduits 26, 36 and the section of bowel 18 provide a closed system for the dialysate, allowing the dialysate to cycle within the prosthesis 120, but preventing the dialysate from leaving the prosthesis 120.

As discussed above, the abdominal sac 64 is generally formed of a semi-permeable membrane having a porosity which precludes the dialysate within the abdominal sac 64 from escaping into the peritoneal region, but still permits unconcentrated urine within the peritoneal region to enter the abdominal sac 64 through osmotic pressure. Because the abdominal sac 64 is required to function in an aqueous environment, it preferably is formed of a synthetic plastic material with some elastic qualities (*e.g.*, gortex-like cloth). However, the abdominal sac 64 should not be so elastic as to expand to an extent that permits the dialysate molecules or microstructures to exit from expanded pores of its walls.

As with the abdominal sacs discussed above, portions of the wall of the abdominal sac 64 may be formed of an impermeable or a substantially impermeable membrane that is more elastic than the semi-permeable membrane and does not permit the dialysate to exit, even when the impermeable or substantially impermeable membrane is expanded beyond its elastic limit. Therefore, before the semi-permeable membrane expands under pressure to an extent that could permit dialysate to exit, the impermeable or substantially impermeable membrane stretches to contain the dialysate while inhibiting the dialysate from exiting therefrom.

The unconcentrated urine and dialysate entering the abdominal sac 64 is directed through the first conduit 26 and the one-way valve 28 through the diaphragm 14 and into the thoracic pouch 16 by the internal body pumping mechanism described above. The unconcentrated urine and dialysate within the thoracic pouch 16 then pass through the Y-

shaped second conduit 36 and the one-way valve 38 therein. The unconcentrated urine and dialysate are then directed through the two conduit sections 124, 126 to a respective one of the bowel segments 128, 132. Movement of the urine and dialysate from the thoracic pouch 16 through the second conduit takes place by the internal body mechanism described above, which may be assisted or supplemented with a pump.

The conduit sections 124, 126 of the second conduit 36, which direct the urine and dialysate into the section of the patient's bowel 18, include a series of apertures 54 so as to allow the urine and dialysate within the conduit sections 128, 132 to flow out of the conduit 36. The semi-permeable filter 138 that is within the bowel 18 has a porosity which precludes the dialysate that filtered through the holes 54 of the second conduit 36 from escaping from the bowel 18 into the appendix 22, distal right ureter 24, or bladder 20, but still permits the urine, now concentrated, to permeate through the bowel 18.

As noted above, when the unconcentrated urine is turned into concentrated urine within the separated section of the patient's bowel 18, most of the concentrated urine will filter through the semi-permeable filter 138 and exit the bowel 18. The concentrated urine will then flow into the urinary bladder 20 to be expelled intermediately, just as in a normally functioning human patient. The dialysate and returning urine is returned through the distal end 134 of the second conduit's second section 126 to the abdominal sac 64 for recirculation.

Referring to Fig. 8 there is shown at 150, an exemplary continuous internal peritoneal dialysis prosthesis inserted within a patient's body in accordance with yet still

another preferred embodiment of the invention, which is similar to the prostheses 10, 62, 70, 80 and 120 discussed above. As shown in Fig. 8, the prosthesis 150 includes an abdominal sac 64 in the abdominal region of the patient below diaphragm 14, a thoracic pouch 16 in the thoracic region of the patient's body above the diaphragm 14, a section of the patient's bowel 18 located within the abdominal section of the patient, and the patient's urinary bladder 20 connected to a downstream end of the bowel 18 through the patient's cecum or appendix 22 and a distal right ureter 24. As described above in the other embodiments, the abdominal sac 64 is connected to the thoracic pouch 16 through a conduit 26, including a one-way valve 28 therein. The one-way valve 28 permits fluid to flow only in the direction of arrow 30 from the abdominal sac 64 into the thoracic pouch 16.

The prosthesis 150 includes a second conduit 36 having a proximal end 152 connected to the thoracic pouch 16, and a distal end 154 connected to the abdominal sac 64. While not being limited to a particular theory, the second conduit 36 passes through the diaphragm 14 and preferably includes a one-way valve 38 near its proximal end 152 to permit fluid (*e.g.*, dialysate and unconcentrated urine) to flow from the thoracic pouch 16 into the peritoneal region only in the direction of arrow 40.

The second conduit 36 of Fig. 8 includes a urine transfer sac 156 arranged to transfer unconcentrated urine to an extension of the second conduit, hereinafter referred to as a third conduit 158. The third conduit 158 includes a urine receiving sac 160 arranged to receive unconcentrated urine from the urine transfer sac 156 and to transfer

the urine to the separated section of bowel 18. To transfer unconcentrated urine from the second conduit 36 to the bowel 18, the third conduit 158 extends through and terminates in the section of bowel 18. The second conduit 36, its extension (the third conduit 158) and the semi-permeable membrane window 166 form a fluid guide member 182 that is adapted to transfer unconcentrated urine from the thoracic pouch 16 via the second and third conduits into the separated section of the patient's bowel 18, and to transfer dialysate from the thoracic pouch 16 via the second conduit to the abdominal sac 64.

The urine transfer sac 156 includes an impermeable outer wall 162, and the urine receiving sac 160 includes an impermeable outer wall 164 coupled to the impermeable outer wall 162. The urine transfer sac 156 and urine receiving sac 160 are separated by a semi-permeable membrane window 166 having pores or apertures that provide the window with a porosity which precludes dialysate within the urine transfer sac 156 from escaping into the urine receiving sac 160, but permits urine within the urine transfer sac 156 to enter the urine receiving sac 160. Therefore, in this example of the preferred embodiment, the dialysate is precluded from entry into the section of bowel 18. Instead, the dialysate continues within a lower section 168 of the second conduit 36 toward the distal end 154. The distal end 154 is provided with a one-way valve 48 to permit the fluid (*e.g.*, dialysate and possibly some urine) to flow only in the direction of arrow 49 from the second conduit 36 into the abdominal sac 64.

As can be seen in Fig. 8, the third conduit 158 includes a one-way valve 170 arranged to permit fluid, such as unconcentrated urine, to flow only in the direction of

arrow 172 from the urine receiving sac 160 toward apertures 54 located downstream from the one-way valve 170. As noted above, the third conduit 158 directs unconcentrated urine from the second conduit 36, and in particular, the urine transfer sac 156, to the section of bowel 18, where the unconcentrated urine is turned into concentrated urine and eventually exits via the urinary bladder 20 intermittently, just as in a normally functioning human patient.

While not being limited to a particular theory, the third conduit 158 has a Y-shaped tubing that bifurcates into a first leg 174 and a second leg 176 downstream from the one-way valve 170. The first leg 174 extends into and terminates within the first bowel segment 128. The second leg 176 extends into and terminates within in the second bowel segment 132. As can be seen in Fig. 8, the first bowel segment 128 is sutured to the first leg 174 of the third conduit 158 at the entrance 178 to the first bowel segment. The second bowel segment 132 is sutured to the second leg 176 at the entrance 180 to the second bowel segment. The first and second legs 174, 176, which direct the unconcentrated urine into the section of the patient's bowel 18, both include a series of apertures 54 large enough to allow the unconcentrated urine within the third conduit 158 to move out of the conduit and into the bowel 18 wherein the section of bowel functions to reabsorb water, electrolytes, and small molecules, resulting in the formation of concentrated urine.

As noted above, the section of the bowel 18 that preferably is selected includes the right colon and ileum, and is capable of 90 percent water reabsorption in the bowel, which

translates to 10 to 20 liters of water per day. Also as noted above, the jejunum is anastomosed to the traverse colon to restore the integrity of the GI tract, and therefor, although the section of patient's bowel 18 is isolated from the GI tract, its blood supply remains intact so as to permit it to function in this invention.

As discussed above, the abdominal sac 64 is generally formed of a semi-permeable membrane having a porosity which precludes the dialysate within the abdominal sac 64 from escaping into the peritoneal region, but still permits unconcentrated urine within the peritoneal region to enter the abdominal sac 64 through osmotic pressure. The abdominal sac 64 is preferably formed of a synthetic plastic material with some elastic qualities. However, the abdominal sac should not be so elastic as to expand to an extent that permits the dialysate molecules or microstructures to exit from expanded pores of its walls.

As with the abdominal sac 64 discussed in other embodiments of this invention, portions of the wall of the abdominal sac 64 may alternatively be formed of an impermeable or a substantially impermeable membrane that is more elastic than the semi-permeable membrane and does not permit the dialysate to exit, even when the impermeable or substantially impermeable membrane is expanded beyond its elastic limit. Therefore, before the semi-permeable membrane expands under pressure to an extent that could permit dialysate to exit, the impermeable or substantially impermeable membrane stretches to contain the dialysate while inhibiting the dialysate from exiting therefrom.

Still referring to Fig. 8, the unconcentrated urine entering the abdominal sac 64 through the semi-permeable membrane, and the dialysate are directed through the first

conduit 26 and the one-way valve 28, through the diaphragm 14 and into the thoracic pouch 16 by the internal body pumping mechanism described above. The unconcentrated urine and dialysate within the thoracic pouch 16 then pass through the second conduit 36 and the one-way valve 38 therein to the urine transfer sac 156. As noted above, the semi-permeable membrane window 166 precludes dialysate from filtering through the window, but allows the urine to pass through and into the urine receiving sac 160. The dialysate is returned, possibly with some urine, through the lower section 168 of the second conduit 36 to the abdominal sac 64 for circulating and recycling. Preferably, the lower section 168 of the second conduit 36 is impermeable to preclude the escape of any urine and dialysate therefrom.

The unconcentrated urine that filters through the semi-permeable membrane window 166 passes through the one-way valve 170 into the bowel 18, wherein the bowel 18 functions to reabsorb water, electrolytes and small molecules resulting in concentrated urine. The concentrated urine exits to the urinary bladder 20, preferably via the distal right ureter 24 which can be attached to the cecum or appendix 22 when appropriate. The concentrated urine is expelled intermittently from the bladder, just as in a normally functioning human patient.

It should be noted that while the apertures 54 have been described in Fig. 1 as being relatively large (*e.g.*, 0.5 cm), the size of the apertures should not be limited to relatively large holes for this embodiment, as the size of the holes only need to be large enough to allow unconcentrated urine to pass from the third conduit into the bowel 18.

The apertures 54 are shown in Fig. 8 by way of example, and should not limit the scope of the invention to apertures of any particular size, as long as the apertures allow urine to flow through.

While not being limited to a particular theory, it should be noted that the diameter of the lower section 168 of the second conduit 36 may be smaller than the diameter of the third conduit to augment the filtering of the unconcentrated urine through the semi-permeable membrane window 166 by creating an environment of higher pressure in the urine transfer sac 156 than in the urine receiving sac 160. It is readily understood that such a pressure differentiation between the interiors of the sacs may increase the transfer rate of the unconcentrated urine through the semi-permeable membrane window 166.

Furthermore, as noted above, the pumping action provided by the breathing cycle of the patient can be augmented, or even supplanted, by another device (*e.g.*, a mechanical or electrical watertight pump) implanted in the person's body in fluid communication with the loop of circulating fluid. Such a pump could be positioned anywhere along the first or second conduits in any of the embodiments, as readily understood by a skilled artisan. If supplanting or augmenting the pumping action provided via the thoracic pouch, the mechanical or electrical pump would preferably be attached to the first or second conduit between the abdominal sac and the section of bowel 18. The mechanical or electrical pump could be connected by wire to a subcutaneous power source (*e.g.*, a battery) in a location where it could be periodically replaced if necessary or desired.

Referring to Fig. 9, there is shown at 184, an exemplary fluid guide member 184 that is similar to the fluid guide member 182 shown in Fig. 8. Like the fluid guide member 182, the fluid guide member 184 shown in Fig. 9 is adapted to transfer unconcentrated urine from a thoracic pouch via the second conduit 36 and third conduit 158 into the separated section of the patient's bowel 18, and to transfer dialysate from the thoracic pouch via the second conduit 36 to an abdominal sac.

As best seen in Fig. 9, the fluid guide member 184 includes a safety outlet 186. The outlet 186 is a pressure relief member arranged to communicate fluid from the second conduit 36 to the section of bowel 18 if the pressure in the prosthesis becomes greater than desired. While not being limited to a particular theory, the safety outlet 186 preferably includes a conduit 188 with a pressure sensitive one-way valve 190 therein. The conduit 188 preferably is attached to the urine transfer sac 156 and is sutured to the section of bowel 18 at an opening 194.

It is understood that the conduit 188 could alternatively attach from another member of the prosthesis 150, such as the abdominal sac 64, first conduit 26, thoracic pouch 16 or second conduit 36 to the section of bowel 18 for removing excess dialysate from the prosthesis to the bowel 18 and eventually out of the patient's body. It is noteworthy that such a pressure relief member communicates dialysate from a part of the prosthesis arranged to contain dialysate to a part of the prosthesis below or after a semi-permeable membrane member, such as the window 166, that filters urine through while

precluding dialysate from filtering through. As shown in Fig. 9, this communication is preferably between the urine transfer sac 156 and the section of bowel 18.

Typically, the pressure in the prosthesis may become greater than desired if too much dialysate is present in the prosthesis. As discussed above, dialysate pulls unconcentrated urine into the prosthesis. If more dialysate is present in the prosthesis than desired, the dialysate may pull so much unconcentrated urine into the prosthesis that the abdominal sac 64 and thoracic pouch 16 become too full to operate efficiently as an internal body pump. Moreover, too much dialysate and unconcentrated urine in the prosthesis could possibly cause the sac 156 to expand beyond its elastic limit, or cause damage to the semi-permeable membrane window 166. Accordingly, the fluid guide member 184 includes the safety outlet 186 to direct dialysate and unconcentrated urine from the urine transfer sac 156 to the section of bowel 18 when the pressure in the sac 156 becomes greater than desired.

The pressure sensitive one-way valve 190 permits fluid to flow only in the direction of arrow 192 from the urine transfer sac 156 to the section of bowel 18 when the pressure at the valve 190 becomes greater than a desired threshold. The desired threshold is preferably set above normal and allowable heightened pressure levels in the urine transfer sac 156, and below a pressure level where damage to the sac 156 or semi-permeable membrane window 166 may occur. For example, a desired threshold may be two to three times the normal operating pressure in the prosthesis.

The safety outlet 186 relieves pressure on the urine transfer sac 156 and window 166 by directing dialysate and unconcentrated urine from the sac 156 directly to the section of bowel 18. This transfer of fluids occurs when the pressure is high enough to open the pressure sensitive valve 190. Under normal circumstances, when the amount of pressure on the urine transfer sac 156 and semi-permeable membrane window 166 is in a desired operating range, there is no need for the valve 192 to open. The pressure sensitive valve 192 only opens when the pressure is above a desired range, such as, when too much dialysate is in the prosthesis, to allow the safety outlet 186 to direct dialysate and unconcentrated urine to the section of bowel 18, and thus, remove dialysate from the prosthesis. The removed dialysis escapes from the bowel 18 into the appendix 22 and eventually exits the patient via the urinary bladder 20 as discussed above.

Referring to Fig. 10 there is shown at 200, an exemplary continuous internal peritoneal dialysis prosthesis inserted within a patient's body in accordance with another preferred embodiment of the invention, which is similar to the prostheses 10, 62, 70, 80, 120 and 150 discussed above. As shown in Fig. 10, the prosthesis 200 includes an abdominal sac 202 in the abdominal region of the patient below diaphragm 14, a thoracic pouch 204 in the thoracic region of the patient's body above the diaphragm 14, a section of the patient's bowel 18 located within the abdominal section of the patient, the patient's urinary bladder 20 connected to a downstream end of the bowel 18 through the patient's cecum or appendix 22 and a distal right ureter 24.

The prosthesis 200 includes or is substantially similar to many features shown in the prosthesis 70 shown in Fig. 3, and in the prosthesis 150 shown in Fig. 8. For example, in addition to the features listed above, the prosthesis 200 includes a fourth conduit 206, a semi-permeable membrane 72, apertures 54 and one way valves 212, 220 substantially similar to the second conduit 36, semi-permeable membrane 72, apertures 54 and one way valves 38, 48 shown in Fig. 3. Further, the prosthesis 200 includes a second conduit 36, a third conduit 158, a urine transfer sac 156, a urine receiving sac 160, a semi-permeable membrane window 166, one-way valves 38, 48, 170, apertures 54, a first segment 128 of the bowel 18 and a second segment 132 of the bowel substantially similar to the like numbered element shown in Fig. 8.

The abdominal sac 202 is substantially the same as previously described abdominal sac 64. As can best be seen in Fig. 10, the abdominal sac 202 is connected to the thoracic pouch 204 through a conduit 26, including a one-way valve 28 therein. The one-way valve 28 permits fluid to flow only in the direction of arrow 30 from the abdominal sac 202 into the thoracic pouch 16. The abdominal sac 202 is also connected to the second conduit 36 and the fourth conduit 206 for receiving dialysate and some urine, as will be described below in greater detail.

The abdominal sac 202 is generally formed of a semi-permeable membrane having a porosity which precludes the dialysate within the abdominal sac 202 from escaping into the peritoneal region, but still permits unconcentrated urine (*e.g.*, ultrafiltrate of blood) within the peritoneal region to enter the abdominal sac 202 through osmotic pressure.

The abdominal sac 202 is preferably formed of a synthetic plastic material with some elastic qualities. However, the abdominal sac should not be so elastic as to expand to an extent that permits the dialysate molecules or microstructures to exit from expanded pores of its walls.

As with the abdominal sacs discussed in other embodiments of this invention, portions of the wall of the abdominal sac 202 may alternatively be formed of an impermeable or a substantially impermeable membrane that is more elastic than the semi-permeable membrane and does not permit the dialysate to exit, even when the impermeable or substantially impermeable membrane is expanded beyond its elastic limit. Therefore, before the semi-permeable membrane expands under pressure to an extent that could permit dialysate to exit, the impermeable or substantially impermeable membrane stretches to contain the dialysate while inhibiting the dialysate from exiting therefrom.

The prosthesis 200 includes a second conduit 36 having a proximal end 152 connected to the thoracic pouch 204, and a distal end 154 connected to the abdominal sac 202. While not being limited to a particular theory, the second conduit 36 passes through the diaphragm 14 and preferably includes a one-way valve 38 near its proximal end 152 to permit fluid (*e.g.*, dialysate and unconcentrated urine) to flow from the thoracic pouch 204 into the peritoneal region only in the direction of arrow 40.

The second conduit 36 of Fig. 10 includes a urine transfer sac 156 arranged to transfer unconcentrated urine to an extension of the second conduit, hereinafter referred to as a third conduit 158. The third conduit 158 includes a urine receiving sac 160

arranged to receive unconcentrated urine from the urine transfer sac 156 and to transfer the urine to the separated section of bowel 18. To transfer unconcentrated urine from the second conduit 36 to the bowel 18, the third conduit 158 includes a distal opening 130, and extends from the second conduit 36 into the first segment 128 of the bowel 18 until it ends at the distal opening. The first bowel segment 128 is sutured to the third conduit 158 at the entrance 178 to the first bowel segment.

As described above in reference to Fig. 8, the urine transfer sac 156 shown in Fig. 10 includes an impermeable outer wall 162, and the urine receiving sac 160 includes an impermeable outer wall 164 coupled to the impermeable outer wall 162. The urine transfer sac 156 and urine receiving sac 160 are separated by a semi-permeable membrane window 166 having pores or apertures that provide the window with a porosity which precludes dialysate within the urine transfer sac 156 from escaping into the urine receiving sac 160, but permits urine within the urine transfer sac 156 to enter the urine receiving sac 160. While not being limited to a particular theory, the dialysate is precluded from entry into the section of bowel 18. Instead, the dialysate continues within a lower section 168 of the second conduit 36 toward the distal end 154. The distal end 154 is provided with a one-way valve 48 to permit the fluid (*e.g.*, dialysate and possibly some urine) to flow only in the direction of arrow 49 from the second conduit 36 into the abdominal sac 202. Preferably, the lower section 168 of the second conduit 36 is impermeable to preclude the escape of any urine and dialysate therefrom.

As can be seen in Fig. 10, the third conduit 158 includes a one-way valve 170 arranged to permit fluid, such as unconcentrated urine, to flow only in the direction of arrow 172 from the urine receiving sac 160 toward apertures 54 located downstream from the one-way valve 170. As noted above, the third conduit 158 directs unconcentrated urine from the second conduit 36, and in particular, the urine transfer sac 156, to the section of bowel 18, where the unconcentrated urine is turned into concentrated urine and eventually exits via the urinary bladder 20 intermittently, just as in a normally functioning human patient.

The fourth conduit 206 has a proximal end 208 connected to the thoracic pouch 204, and a distal end 210 connected to the abdominal sac 202. Like the above discussed conduits 26, 36, and 158, the fourth conduit 206 is preferably made from silicon plastic, which is inert and does not cause peritoneal irritation. While not being limited to a particular theory, the fourth conduit 206 passes through the diaphragm 14 and preferably includes a one-way valve 212 near its proximal end 152 to permit fluid (*e.g.*, dialysate and unconcentrated urine) to flow from the thoracic pouch 204 into the peritoneal region and bowel 18 only in the direction of arrow 214. The thoracic pouch 204 is substantially similar to the thoracic pouch 16 described in the preferred embodiments above. Further to the thoracic pouch 16 described above, the thoracic pouch 204 includes an additional port connected to the fourth conduit 206 for permitting fluid to flow from the thoracic pouch 204 into the fourth conduit.

Still referring to Fig. 10, the patient's bowel 18 includes end sections sutured to the fourth conduit 206 at both an entrance 216 to the second segment 132 of bowel 18 and an exit 218 from the bowel 18. The distal end 210 of the fourth conduit 206 extends through a lower end of the bowel 18 and is connected to the abdominal sac 202 to recycle the flow of dialysate and urine back into the abdominal sac. The distal end 210 is provided with a one-way valve 220 to permit the urine to flow only in the direction of arrow 222 from the patient's bowel 18 to the abdominal sac 202.

The fourth conduit 206 is substantially similar to the second conduit 36 shown in Fig 3. For example, the fourth conduit 206 includes a series of relatively large holes 54 that allow urine and dialysate to permeate from the conduit into the semi-permeable membrane 72. The semi-permeable membrane 72 extends about the fourth conduit 206 within the bowel 18 and is attached to the fourth conduit at both an entrance 74 to the membrane 72 and the exit 76 from the membrane 72. The semi-permeable membrane 72 is preferably a synthetic plastic material with some elastic qualities having a porosity which precludes dialysate from filtering through the semi-permeable membrane, but permits unconcentrated urine to filter through the material into the bowel 18, wherein the bowel 18 functions to reabsorb water, electrolytes and small molecules resulting in concentrated urine.

A fluid guide member 228 includes the conduits and filters that are adapted to transfer unconcentrated urine form the thoracic pouch 204 into the separated section of bowel 18, and to transfer dialysate from the thoracic pouch to the abdominal sac 202.

Referring to Fig. 10, the fluid guide member 228 includes the second, third, and fourth conduits 36, 158, 206, the semi-permeable membrane window 166, the semi-permeable membrane 72, and the one-way valves located in the conduits.

As noted above, the section of the bowel 18 that preferably is selected includes the right colon or cecum and the ileum. The section of bowel 18 is capable of 90 percent water reabsorption, which translates to 10 to 20 liters of water per day. Referring to Figs. 7, 8 and 10, the first bowel segment 128 is preferably the right (ascending) colon and the second bowel segment 132 is preferably the ileum. Also as noted above, the jejunum is anastomosed to the traverse colon to restore the integrity of the GI tract, and therefor, although the section of patient's bowel 18 is isolated from the GI tract, its blood supply (*e.g.*, arterial and venous) remains intact so as to permit it to function in this invention.

As also noted above, the pumping action provided by the breathing cycle of the patient can be augmented, or even supplanted, by another device (*e.g.*, a mechanical or electrical watertight rate adjustable pump) implanted in the person's body in fluid communication with the loop of circulating fluid. Such an adjustable pump for circulating fluid within the prosthesis 200 is shown at 224 along the first conduit 26. The mechanical or electrical pump 224 shown in Fig. 10 preferably includes a battery that provides power to the pump for moving fluid in the first conduit 26 from the abdominal sac 202 to the thoracic pouch 204 in the direction of the arrow 226. As an alternative, the pump 224 could be connected by a wire to a subcutaneous power source (*e.g.*, a battery)

in a location where it could be periodically replaced if necessary or desired as understood by a skilled artisan.

In operation, the unconcentrated urine entering the abdominal sac 202 through the semi-permeable membrane and the dialysate are directed through the first conduit 26 and the one-way valve 28, through the diaphragm 14 and into the thoracic pouch 204 by the internal body pumping mechanism, and if desired, by the pump 224 described above. Unconcentrated urine and dialysate within the thoracic pouch 204 pass through the second conduit 36 and the one-way valve 38 therein to the urine transfer sac 156. As noted above, the semi-permeable window 166 precludes dialysate from filtering through the window, but allows the urine to pass through and into the urine receiving sac 160. The dialysate is returned, possibly with some urine, through the lower section 168 of the second conduit 36 to the abdominal sac 202 for recirculating and recycling.

Unconcentrated urine and dialysate within the thoracic pouch 204 also pass through the fourth conduit 206 and the one-way valve 212 therein to the second segment 132 of the patient's bowel 18. Movement of the unconcentrated urine and dialysate from the thoracic pouch 204 through the fourth conduit 206 takes place by the internal pumping mechanism described above, which may be assisted or supplemented with the pump 224. The fourth conduit 206 includes a series of relatively large holes 54 so as to allow the unconcentrated urine and dialysate within the fourth conduit to flow out of the conduit within the semi-permeable membrane 72. The semi-permeable membrane 72, which is within the bowel 18 has a porosity which precludes the dialysate that filtered through the

holes 54 of the second conduit 36 from escaping into the bowel 18, but still permits the unconcentrated urine to permeate. The dialysate is returned, possibly with some urine, through the fourth conduit 206 to the abdominal sac 202 for recirculating and recycling.

The unconcentrated urine that filters through the semi-permeable membrane window 166 passes through the one-way valve 170 and apertures 54 into the bowel 18. The unconcentrated urine that permeates through the semi-permeable membrane 72 passes into the bowel 18. The bowel 18 functions to reabsorb water, electrolytes and small molecules resulting in concentrated urine. The concentrated urine exits to the urinary bladder 20, preferably via the distal right ureter 24 which can be attached to the cecum or appendix 22 when appropriate. The concentrated urine is expelled intermittently from the bladder, just as in a normally functioning human patient.

It should be noted that the apertures 54 have been described in Fig. 1 as being relatively large (*e.g.*, 0.5 cm). The size of the apertures 54 should not be limited to relatively large holes for this embodiment, as the size of the apertures only need to be large enough to allow unconcentrated urine to pass from the third and fourth conduits into the bowel 18. The apertures 54 are shown in Fig. 10 by way of example, and should not limit the scope of the invention to apertures of any particular size, as long as the apertures allow urine to flow through.

While not being limited to a particular theory, it should be noted that the diameter of the lower section 168 of the second conduit 36 may be smaller than the diameter of the third conduit 158 to augment the filtering of the unconcentrated urine through the semi-

permeable window 166 by creating an environment of higher pressure in the urine transfer sac 156 than in the urine receiving sac 160. It is readily understood that such a pressure differentiation between the interiors of the sacs may increase the transfer rate of the unconcentrated urine through the semi-permeable window 166.

As an alternative embodiment to the embodiment shown by example in Fig. 10, it is understood that the second conduit 36 and fourth conduit 206 could be merged at either or both of their proximal or distal ends, before the merged conduit attaches to one of the thoracic pouch 204 or the abdominal sac 202. For example, instead of attaching both the second and fourth conduits to the thoracic pouch 204, the fourth conduit 206 could be attached to the second conduit 36, preferably below the one-way valve 38. An advantage of this alternative embodiment is that the one-way valve 38 permits fluid to flow from the thoracic pouch 204 to both the second and fourth conduits, rendering the one-way valve 212 previously in the fourth conduit 206 unnecessary. This arrangement also provides the benefit that the thoracic pouch 204 does not attach directly to the fourth conduit 206 and thus does not require an attachment port for the fourth conduit. Further, the fourth conduit 206 does not pass through the diaphragm 14. This arrangement of thoracic pouch 204 and conduits 36, 206 closely resembles the thoracic pouch 16 and second conduit 36 shown in Fig. 7, with the second conduit bifurcating into conduit sections 124 and 126.

As another example of an alternative embodiment to the embodiment shown by example in Fig. 10, instead of attaching both the distal end 154 of the second conduit 36

and the distal end 210 of the fourth conduit 206 to the abdominal sac 202, the distal end of the fourth conduit could be attached to the distal end of the second conduit, preferably before the one-way valve 48. An advantage of this alternative embodiment is that the one-way valve 48 permits fluid to flow from both the second and fourth conduits to the abdominal sac 202, rendering the one-way valve 220 previously in the fourth conduit unnecessary. This arrangement also provides the benefit that the abdominal sac 202 does not attach directly to the fourth conduit 206 and thus does not require an attachment port for the fourth conduit. In this arrangement, the abdominal sac 202 is substantially identical to the abdominal sac 64 described above.

The examples of the alternative embodiments to the embodiment shown in Fig. 10 attach the fourth conduit 206 to the second conduit 36, instead of attaching the fourth conduit to either or both of the thoracic pouch 204 and abdominal sac 202. While not being limited to a particular theory, it is understood that the alternative embodiments could likewise attach the second conduit 36 to the fourth conduit 206, instead of attaching the second conduit to either or both of the thoracic pouch 204 and abdominal sac 202.

It is understood that the size of the sacs, pouches, filters and conduits are preferably determined in accordance with several factors, such as the flow rate desired, the rate of clearance of wastes, and the size, metabolism, fluid intake, nutritional status, cardiac output, thickness of blood and concentration of blood of the patient. For example, an abdominal sac would be larger for an adult (e.g., 500 cc -1000 cc) than for a child (e.g.,

200 cc - 500 cc). The amount of dialysate preferred in the prosthesis would likewise be affected by the size of the prosthesis and the desired output.

Yet another advantage of the prostheses described above is that they are generally made of an inert plastic regularly used inside the body for other purposes, as discussed above and readily understood by a skilled artisan. An entire prosthesis weighs less than about a pound, and preferably weighs less than about three ounces. Moreover, once implanted into a patient, the prosthesis is not visible and anatomical structures operate in their natural positions in the body.

It should be apparent from the aforementioned description and attached drawings that the concept of the present application may be readily applied to a variety of preferred embodiments, including those disclosed herein. For example, in Fig 3. the distal end 46 of the second conduit 36 may include relatively large holes so as to allow unconcentrated urine and dialysis in the peritoneum to flow into the conduit 36 and the abdominal sac 64. Likewise, In Fig. 2, the central section 66 of the second conduit 36 has a semi-permeable wall, and can also include relatively large holes 54, as shown in the bowel 18 of Fig. 3. Similarly, in lieu of the relatively large holes 54 located in the second conduit 36 and the semi-permeable membrane 72 within the bowel 18 of Fig. 3, the conduit 36 within the bowel 18 can be constructed like the central region 66 of the conduit 36 shown in Fig. 2. That is, in Fig.3, the conduit 36 within the bowel 18 can be formed of a semi-permeable membrane. Moreover, in Fig. 4, instead of coupling the distal end of the second conduit to the dialysis sac 84, the distal end may extend to and end in the peritoneal space to

return a percentage of the fluid to the peritoneum. In this example the distal end 46 of the conduit 36 should either be of a very small diameter, or employ a moderate pressure one-way valve 46 therein to control the flow of fluid into the peritoneal space in a manner that allows adequate residence time for the bowel to absorb water from the unconcentrated urine passing therethrough, but not such as to prevent flow of partially concentrated urine into the peritoneal space for lymphatic reabsorption and recycling through the entire system. Furthermore, in Figs. 7 and 8, instead of having two sections or legs of a conduit communicate within the bowel, it is understood that the conduit could be constructed so that any number of sections or legs, including one, would extend into and communicate within the bowel. In addition, the ureter 24 could be connected directly to the bowel 18, thus bypassing the appendix 22. In this preferred embodiment, the appendix 22 would not be used.

It is within the scope of the invention that features of the exemplary embodiments discussed above can also be used in other of the exemplary embodiments. For example, as an alternative to the disk filter 138 shown in Fig. 7, the semi-permeable membrane 72 shown in Fig. 3 could be used to extend about the conduits in the section of bowel 18. Moreover, portions of the first leg 174 and second leg 176 of the third conduit 158 that extend into the bowel 18 could alternatively be formed of a semi-permeable membrane, as shown for the second conduit 36 in Fig. 2. In addition, while not preferred, the first conduit 26 of any of the embodiments could include apertures 54, as shown in Fig. 3. Also, the conduits shown in Fig. 10 could be augmented or replaced by other conduits as

shown by example in Figs. 1-9. For example, the fourth conduit 206 could be supplanted by a conduit having the structure exemplified by the second conduit 36 of Fig. 2.

Without further elaboration the foregoing will so fully illustrate my invention that others may, by applying current or future knowledge, readily adapt the same for use under various conditions of service.